

HEALTH SERVICES QUALITY IMPROVEMENT IMPLEMENTATION GUIDE

EXERCISE THIRTEEN

SUBJECT: PATIENT NOTIFICATION OF THE RESULTS OF CERTAIN LABORATORY PROCEDURES

PURPOSE: To develop a reliable and reviewable method of ensuring that patients are notified of the results of certain laboratory procedures which have a significant impact on their health and well-being.

DISCUSSION:

1. The results of certain laboratory tests have such a significant impact on the patient that practitioners must, as part of good medical practice, notify the patient of the results. These tests include:
 - a. All biopsies
 - b. All pap smears
 - c. All pregnancy tests
 - d. All tests whose results indicate a need to initiate or change treatment.
2. Each clinic must develop a protocol [see enclosure (1)] which allows tracking laboratory tests results to ensure that patients are notified of results when indicated. It must also provide for medical or dental officer review of the results prior to the patient being notified. At a minimum, the protocol must require that:
 - a. All laboratory requests (SF-546 through SF-557) include the name of the responsible medical or dental officer and the patient's telephone number.
 - b. A reviewable laboratory specimen log must be kept which lists all tests performed with information necessary to track the specimen. Enclosure (2), is a sample log, which can be used in whole or in part for this purpose.
 - c. A medical or dental officer, as appropriate, reviews all laboratory results.
 - d. A medical or dental officer determines, for each result, if the patient should be notified and documents the decision on the report form; for example, by initialing the report and noting either "action necessary" or "no action necessary".
3. The protocol may allow the use of a pre-addressed mailer to expedite the notification process for patients who cannot be or don't need to be contacted by telephone [see enclosures (3) through (6)]. The Clinic Automated Management System (CLAMS) or other computer system can also be used to generate form letters to notify patients of both positive and negative pap smear and pathology results. Enclosures (7) negative Pap Smear, (8) positive Pap Smear, and (9) Biopsy are samples of CLAMS generated letters. The patient's name and address are placed so that the letter can be used with a window envelope.

ACTION: All clinics will develop a protocol that details a reliable, reviewable system to ensure that all laboratory tests which require action are identified and reviewed by a medical or dental officer. All pap smears, biopsies, pregnancy tests, and any test results, which require action must be reported to the patient. Documentation of patient notification must be noted by the medical or dental officer on the lab report form. Document required follow-up action and recommendations on a SF 600. Samples of a protocol, logs, mailer format, and CLAMS generated form letters, provided as enclosures (1) through (9), may be used for this purpose, in whole or in part.

- Encl.: (1) Sample Protocol, Patient Notification of the Results of Certain Laboratory Procedures
(2) Sample, Laboratory Specimen Log
(3) Sample, Self-addressed mail notification form, negative biopsy/ laboratory results
(4) Sample, Self-addressed mail notification form, positive biopsy/ laboratory results
(5) Sample, Self-addressed negative/benign pap smear notification form
(6) Sample, Self-addressed positive pap smear notification form
Explanation: Enclosures (5) and (6) were derived from MEDDAC Form 20, Sept 97, used by Army OB-GYN clinic)
(7) Sample, CLAMS-generated form letter, negative pap result
(8) Sample, CLAMS-generated form letter, positive pap result
(9) Sample, CLAMS-generated form letter, biopsy result

SAMPLE

SAMPLE

CLINIC PROTOCOL

PURPOSE: To develop a reliable and reviewable method of ensuring that patients are notified of the results of certain laboratory procedures which have a significant impact on their health and well-being.

DISCUSSION:

1. The results of certain laboratory tests have such a significant impact on the patient that we must, as part of good medical practice, notify the patient of the results.
2. The notification decision must be made by the responsible medical or dental officer in each case, based on a combination of the test results and the patient's condition. A health services technician may not assume responsibility for notifying patients of laboratory results.
3. The laboratory technician, after performing the test or after logging in results from the reference laboratory will forward the results to the responsible medical or dental officer.
4. The medical or dental officer will indicate on the lab report which reports require patient notification and which do not, and will initial and date the report. At a minimum, notification must be provided for the following:
 - a. All biopsy results
 - b. All pap smear results
 - c. All pregnancy test results
 - d. All test results which necessitate initiation of or a change in treatment.
5. Reports not requiring further action will be returned to the laboratory technician who will indicate in the specimen log that no further action is required.
6. Reports requiring action – usual action:
 - a. All pap smears and biopsies – Medical or dental officer may phone patient, or send negative/ benign results by self addressed mailer, computer form letter, or CLAMS-generated form letter. When unable to contact patients with positive/malignant results, mail letter instructing the patient to contact medical officer at their earliest convenience with return receipt requested. Time mailing such that patient receives the notification during the first part of the week (Monday – Wednesday). Lab must continue to track mailed result forms to ensure patients are eventually contacted. Lab should maintain signed receipt form with the positive/ malignant result.
 - b. Pregnancy test – Medical officer phones the patient. For patients who cannot be contacted by phone, send self-addressed mailer or form letter directing the patient to phone the medical officer.

- c. In all cases, the lab report will be returned to the laboratory technician who will make an appropriate entry on the specimen log indicating the medical or dental officer's decision regarding notification. Lab will maintain log sheets containing general lab results for at least two years. Lab will maintain forms with Pap smear and biopsy results/ notifications for at least ten years.
7. The Chief, Health Services Division (HSD) will ensure that all Health Services staff are familiar with this protocol and comply with its contents. The Chief, HSD or his/her designee will periodically review the specimen log to ensure that the responsible medical or dental officer has acted upon all specimens in the log.

Chief, Health Services Division

Effective Date _____

Laboratory Patient Log

[illegible]

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**MAILER FOR PATIENT NOTIFICATION
NEGATIVE BIOPSY, OR LABORATORY TEST RESULTS**

(delete above prior to mailing)

**USCG CLINIC
(NAME OF YOUR UNIT)
(CLINIC PHONE NUMBER)**

Dear _____

The results of your biopsy/ laboratory test(s) are negative. No further treatment or testing is required at this time. Should you have any questions, please contact the clinic.

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**MAILER FOR PATIENT NOTIFICATION
POSITIVE BIOPSY, OR LABORATORY TEST RESULTS**

(Delete above prior to mailing)

**USCG CLINIC
(NAME OF YOUR UNIT)
(CLINIC PHONE NUMBER)**

Dear _____

The results of your biopsy/ laboratory test(s) are available. Please contact
_____ at the clinic to discuss the results and follow up care.

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NAME OF CLINIC

NORMAL/ BENIGN PAP SMEAR NOTIFICATION

Dear Ms. _____

Sponsor SSN# _____

Your Pap Smear done on _____ showed the following results:

() WITHIN NORMAL LIMITS: No abnormal cells were seen. Please schedule your next Pap smear in 1 year, unless your healthcare provider instructed you otherwise.

() SATISFACTORY FOR EVALUATION BUT LIMITED: The specimen was adequate for evaluation, but limited by the absence of a particular type of cell, inflammation or obscuring blood. Please schedule your next Pap smear in _____.

() BENIGN CELLULAR CHANGES: Minor changes of cervical or vaginal cells because of microbes such as yeast, trichomonas or bacterial vaginosis etc. If you are having symptoms, please call your provider for a prescription. Repeat your Pap smear in 1 year.

() REACTIVE CHANGES: A response of the cervical or vaginal cells to the local environment, appearing slightly irregular. This condition can be seen due to inflammation, infection, menopausal changes or healing after surgery or pregnancy. Please repeat pap smear in 4 to 6 months.

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NAME OF CLINIC

PAP SMEAR NOTIFICATION

Dear Ms. _____

Sponsor SSN# _____

Date of exam: _____

Please contact _____ at _____ at your earliest convenience.

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NAME OF CLINIC

NORMAL PAP SMEAR NOTIFICATION

6400

March 8, 1999

Ms _____
54321 6th Street
Elizabeth City, NC 27909

Dear Ms _____

I have reviewed the results of your recent Pap report and am pleased to inform you that no abnormalities or any concern were discovered.

If you have any questions or are uncertain as to when you should schedule your next screening examination, please call me at (000) 000-0000.

Sincerely,

Dr. _____
Captain, U.S. Public Health Service
Senior Medical Officer
By direction of the Commanding Officer

ENCLOSURE 7

SAMPLE

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NAME OF CLINIC

PAP SMEAR RESULT NOTIFICATION

6400
March 8, 1999

Ms _____
54321 6th Street
Elizabeth City, NC 27909

Dear Ms _____

I have reviewed the results of the Pap smear taken for you in our facility on _____. The report has raised a question regarding one or more abnormalities looked for on a Pap smear.

Most of these questions are resolved by a repeat Pap smear, a course of therapy, or further gynecological attention. Please make an appointment at your earliest convenience so we can follow up on this matter.

Sincerely,

Dr. _____
Captain, U.S. Public Health Service
Senior Medical Officer
By direction of the Commanding Officer

ENCLOSURE 8

SAMPLE

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NAME OF CLINIC

NEGATIVE BIOPSY NOTIFICATION

6400

March 8, 1999

Mr. S. Burns
54321 Main Street
Clearwater, FL 34622

Dear Mr. S. Burns

I have received the results of your recent biopsy and am pleased to inform you that the pathologist's diagnosis does not raise any cause for concern.

If you have any questions or are concerned on how to proceed, please call me at (000) 000-0000.

Sincerely,

Dr. _____
Captain, U.S. Public Health Service
Senior Medical Officer
By direction of the Commanding Officer

ENCLOSURE 9